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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,886	01/18/2000	Gale E. Smith	674506-2035.2	1236

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 10/17/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/484,886

Applicant(s)

SMITH ET AL.

Examiner

DR. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002 (Paper Number 8).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) 1-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 43-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The assigned Art Unit and Examiner to your application in the USPTO have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1651.
2. Applicants' response filed July 18, 2002 (Paper Number 8) to election requirement in Office Action of March 18, 2002 (paper number 7) is acknowledged and entered.
3. Claims 1-95 are pending.

Restriction/Election

4. Applicants' election with traverse of Group I, Claims 43-95 filed July 18, 2002 (Paper Number 8) in response to Office Action dated March 18, 2002 (paper number 7) is acknowledged and entered.
5. Applicants' traversal regarding the restriction requirement on pages 2- 3 of the Office Action dated March 18, 2002 (paper number 7) is on the grounds that a search of all the groups would not place an additional burden on the examiner because the apparatus of invention in Group I has to be used for practicing the methods in Group II. Furthermore, the Examiner who placed the restriction requirement in the instant application has examined Claims 1-95 in the corresponding international application PCT/US 00/01568. Applicants' arguments are not found persuasive because the criteria for examination of an application filed under PCT are different than those for an application that is filed under 35 U.S.C. § 111(a) and for the reasons of record on pages 2-3 in Office Action of May 21, 2002 (paper number 7). Moreover, the search for each of the distinct inventions of Groups I-II is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application.

Accordingly, Claims 1-42 are withdrawn from further consideration as being directed to a non-elected invention (i.e., apparatus). See 37 CFR 1.142(b) and MPEP § 821.03.

6. Further review of Claims 43-95 elected for prosecution in this application shows that a restriction under 35 U.S.C. 121 is required to one of the following inventions as outlined below:

- Group I, consisting of claims 43-49 and 85 drawn to a method to culture cells in a bioreactor, classified under Class 435, subclass 325 or 41, for example.
- Group II, consisting of claims 50-72 and 74-85 drawn to a second method of cultivating cells in a bioreactor via recycling through a dialysis means, classified under Class 435, subclass 383, for example.
- Group III, consisting of claims 73, 86-89 and 91-95 drawn to a method to produce an expression product, classified under Class 435, subclass 358, for example.
- Group IV, consisting of Claim 90 drawn to an expressed product, classified under Class 435, subclass 243, for example.

7. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-II are each directed to different inventions, which are not connected in design, operation and/or effect. These methods are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice both the methods at the same time to practice just one method alone.

Inventions in Groups I and II are unrelated to invention in Group III because they are directed to different methods that are not connected in design, operation and/or effect. These methods are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the two methods at the same time to practice just one method alone (MPEP § 806.04, MPEP § 808.01). In the instant case, different inventions disclosed in the claims encompassing inventions in Groups I - III are each methods to cultivate cells or to produce a product, however, each one of them will not be simultaneously applicable (e.g., cells will not be cultivated and collected at the same time as the expression vector product).

Inventions in Groups I and II are unrelated to invention in Group IV because they are directed to different methods that are not connected in design, operation and/or effect. These methods are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice all the three inventions at the same time to practice just one invention alone (MPEP § 806.04, MPEP § 808.01). In the instant case, different inventions disclosed in the claims encompassing inventions in Groups I and II are each methods to cultivate cells, whereas the invention encompassing claim in group IV is drawn to a product that is not prepared by the method recited in invention encompassing claims of Groups I-II.

Inventions in Groups III and IV are related to each other as product and process to make the said product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of Invention III to prepare expressed product can also be applied to prepare any fermentation product (e.g. a dicarboxylic acid or an enzyme). The product claimed in Invention of Group IV may also be prepared by different methods, for example growing the vector on an agar plate in an incubator.

The inventions discussed above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (class and subclass), and their recognized diverse subject matter, restriction for examination purposes as indicated is proper.

8. Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the


currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

9. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

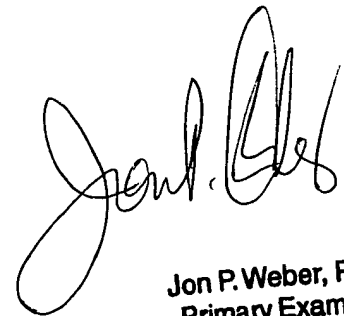
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

October 16, 2002



Jon P. Weber, Ph.D.
Primary Examiner